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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,986	01/17/2002	Richard John Warby	12654-38018	5632

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EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/047,986

Applicant(s)

WARBY, RICHARD JOHN

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10, 15, 16. 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after non-final rejection. Applicant's submission filed on 10/17/2003 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 41 recites that the layer is a cold plasma polymerized siloxane, which contradicts the independent claims 32 and 35, which recites that the method does not use siloxane. Therefore, the claim is indefinite.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,576,068 to Caburet et al. in view of US 4,656,083 to Hoffman et al.

Caburet teaches a method comprising the step of using cold plasma polymerization to create a layer of one or more cold plasma polymerized monomers bonded to at least a portion of one or more internal surfaces of an apparatus for dispensing a medicament (col. 1, lines 6-12), which surfaces come into contact with medicament during storage or dispensing, wherein the apparatus is not a pressurized container of the medicament or a metering valve for a pressurized container. Caburet is silent with regards to the layer not being a cold plasma polymerized siloxane or silazane.

Hoffman teaches a method comprising the step of using cold plasma polymerization to create a layer of one or more cold plasma polymerized monomers bonded to at least a portion of one or more internal surfaces of a medical apparatus, wherein layer is not a cold plasma polymerized siloxane or silazane, wherein the monomers used for cold plasma polymerization is tetrafluoroethylene (col. 5, line 21).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any polymer, including the polymers taught by Hoffman, to create the layer of Caburet because it is well known in the art to use different types of polymers for cold plasma polymerization. Furthermore, the applicant has not disclosed why creating a layer not using siloxane or silazane provides any advantage over a layer using siloxane or silazane.

6. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,131,566 to Ashurst et al. in view of US 4,265,276 to Hatada et al.

Ashurst teaches a method comprising the step of using cold plasma polymerization to create a layer of one or more cold plasma polymerized monomers bonded to at least a portion of one or more internal surfaces of an apparatus for dispensing a medicament, which surfaces come into contact with medicament during storage or dispensing, wherein the layer is not a cold plasma polymerized siloxane or silazane. Ashurst is silent with regards to the layer not being a cold plasma polymerized fluorinated hydrocarbon.

Hatada teaches a method comprising the step of using cold plasma polymerization to create a layer of one or more cold plasma polymerized monomers bonded to at least a portion of one or more internal surfaces of a medical apparatus, wherein layer is not a cold plasma polymerized siloxane, silazane or a fluorinated hydrocarbon. Hatada teaches the use of vinylidene chloride (col. 2, line 11).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any polymer, including the vinylidene chloride polymer taught by Hatada, to create the layer of Ashurst because it is well known in the art to use different types of polymers for cold plasma polymerization. Furthermore, the applicant has not disclosed why creating a layer not using siloxane, silazane or fluorinated hydrocarbon provides any advantage over a layer using vinylidene chloride.

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7. Claims 35-40 and 42-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Ashurst et al. in view of Hatada et al. and in further view of US 5,349,944 to Chippendale et al.

The combination of Ashurst/Hatada teaches the apparatus as being a metered dose inhaler but is silent with regards to the specific components of the inhaler.

Chippendale teaches a metered dose inhaler having a metering valve comprising a valve stem 5 co-axially slidable within a valve member, the valve member and valve stem defining an annular metering chamber, outer and inner rubber annular seals 3,4 operative between the respective outer and inner ends of the valve member and the valve stem to seal the annular metering chamber therebetween. Chippendale also teaches the metered dose inhaler having a housing adapted to receive a container having said metering valve, a mouthpiece, and a duct.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the metered dose inhaler of Ashurst include the specific components of Chippendale because it is well known in the art to have a metering valve in a metered dose inhaler. Furthermore, it would have been obvious to have the different recited components include a layer of cold plasma polymerized polymer because Ashurst teaches that any part of the metered dose inhaler could have a layer of polymerized polymers.

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8. Claims 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,576,068 to Caburet et al., in view of US 4,656,083 to Hoffman et al., in view of US 6,131,566 to Ashurst et al., and in further view of US 5,349,944 to Chippendale et al.

The above combination of Caburet/Hoffman teaches a method of adding a layer of cold plasma polymerized polymer to a medical device used for storing pharmaceutical drugs but is silent with regards to the specifics of the medical storage device. Chippendale teaches a medical device used for storing pharmaceutical drugs having a metering valve comprising a valve stem **5** co-axially slidable within a valve member, the valve member and valve stem defining an annular metering chamber, outer and inner rubber annular seals **3,4** operative between the respective outer and inner ends of the valve member and the valve stem to seal the annular metering chamber therebetween. Chippendale also teaches the metered dose inhaler having a housing adapted to receive a container having said metering valve, a mouthpiece, and a duct. Ashurst teaches a method of providing a layer of cold plasma polymerized polymer to all or part the internal surfaces of a metered dose inhaler (see abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to create a layer of cold plasma polymerized polymers to the device of Chippendale because Caburet teaches that adding a layer to medical storage devices prevents contamination of the products packaged (Caburet; col. 1, lines 6-12). Furthermore, it would have been obvious to add a layer of cold plasma polymerized polymer to the components taught by Chippendale because Ashurst

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teaches that any part of the metered dose inhaler could have a layer of polymerized polymers to prevent adhesion.

9. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,576,068 to Caburet et al. in view of US 4,656,083 to Hoffman et al.

Caburet teaches a method comprising the step of using cold plasma polymerization to create a layer of one or more cold plasma polymerized monomers bonded to at least a portion of one or more internal surfaces of an apparatus for dispensing a medicament (col. 1, lines 6-12), which surfaces come into contact with medicament during storage or dispensing, wherein the apparatus is not a pressurized container of the medicament or a metering valve for a pressurized container; wherein the layer is not of a cold plasma polymerized fluorinated hydrocarbon. Caburet is silent with regards to the layer not being a cold plasma polymerized siloxane or silazane.

Hatada teaches a method comprising the step of using cold plasma polymerization to create a layer of one or more cold plasma polymerized monomers bonded to at least a portion of one or more internal surfaces of a medical apparatus, wherein layer is not a cold plasma polymerized siloxane, silazane or a fluorinated hydrocarbon. Hatada teaches the use of vinylidene chloride (col. 2, line 11).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any polymer, including the polymer taught by Hoffman, to create the layer of Caburet because it is well known in the art to use different types of polymers for cold plasma polymerization. Furthermore, the applicant



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has not disclosed why creating a layer not using siloxane, silazane or a fluorinated hydrocarbon provides any advantage over a layer using siloxane or silazane.

***Response to Arguments***

10. Applicant's arguments with respect to claims 32-47 have been considered but are moot in view of the new ground(s) of rejection.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who whose telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

dpe

  
**GLENN K. DAWSON**  
**PRIMARY EXAMINER**